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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

7590 12/27/2005

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/977,826

Applicant(s)

GOICOECHEA ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,22-25,27-33,39,41 and 43-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,22-25,31-33,39,41,43-49 is/are rejected.
- 7) ☒ Claim(s) 27-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 10-06-05 have been fully considered but they are not persuasive.
2. Regarding the rejection under 35 USC 112 of claims 56 and 57, Applicant contends support is provided at p9 lines 15-19, p 10 lines 1-7, p23 lines 20-23, and p44 lines 19-23. Examiner acknowledges the cited passages to recite the end hoops being perpendicular to the longitudinal axis, but this does not provide support for the limitation "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member".
3. Applicant contends Cragg fails to disclose hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent. Examiner disagrees because the hoops are substantially perpendicular, i.e. greater than 50% perpendicular to the longitudinal axis. Merriam Webster's Collegiate Dictionary 10<sup>th</sup> Ed. defines substantial as "being largely but not wholly that which is specified". Furthermore, Applicant's specification has not defined the scope of "substantially perpendicular" so the broadest reasonable interpretation may include at least 90,80,70 or 60 degrees from the longitudinal axis.
4. With regard to applicant's arguments in the final paragraph of page 3, Applicant contends the Examiner's interpretation of "substantially perpendicular" in the specification implies a rejection under 112 1<sup>st</sup> paragraph. The Examiner disagrees because the position taken is "substantially perpendicular" may be broadly interpreted

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because Applicant has not defined "substantially perpendicular" to mean "perpendicular".

5. Applicant contends Fontaine fails to disclose hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent and vertices of each hoop lie in a common plane perpendicular to the longitudinal axis of the stent. Examiner disagrees because the hoops are substantially perpendicular, i.e. greater than 50% perpendicular to the longitudinal axis. Merriam Webster's Collegiate Dictionary 10<sup>th</sup> Ed. defines substantial as "being largely but not wholly that which is specified". Furthermore, Applicant's specification has not defined the scope of "substantially perpendicular" so the broadest reasonable interpretation may include at least 90,80,70 or 60 degrees from the longitudinal axis.

6. Applicant contends Wolff fails to disclose means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop. Examiner disagrees because element 14 connects juxtaposed apices of neighboring hoops. It is irrelevant that Wolff defines the element 14 as a hinge. The structure of the hinge meets the structural limitation of applicant's means for connecting apices. Regarding claims 54 and depending claims 43-44 in view of figure 1 of Wolff, the stent may be defined as the two adjacent hoops (12,12 on the right side) and means 14 for connecting the apices of the hoops. The radiopaque element would be the element 14 on the left side. Regarding arguments based on the limitation "juxtaposed", Examiner does not understand how Wolff's apices of adjacent hoops are not juxtaposed. Wolff discloses a spacing

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between the apices, but juxtaposed does not inherently exclude a spacing or a particular amount of spacing.

7. In regard to Furui, Applicant relies on their interpretation of "juxtaposed" to define a level of spaced relationship. The definition of juxtaposed is "side by side" and is synonymous with adjacent and does not imply contact (Merriam Webster's Collegiate Dictionary 13<sup>th</sup> Ed.). The apices of Furui figure 1 are clearly adjacent, juxtaposed, or side-by-side.

8. In regard to Wolff in view of Piplani Applicant contends Piplani does not provide a prima facie case of obviousness because Piplani applies the markers to a graft rather than a stent. Examiner disagrees because the Piplani reference is cited to teach obviousness of utilizing platinum and gold for the radiopaque marker disclosed in Wolff. Piplani and Wolff are analogous art (vascular repair devices) and one of ordinary skill in the art would look at stent-graft markers because both are used for the same purpose.

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 56-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. Specifically, claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" which is not disclosed in the specification.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 20,22-24,31-33,41,54,55 are rejected under 35 U.S.C. 102(e) as being anticipated by Cragg US PN 5,405,377.

Cragg discloses in figures 1-4 and line 40 of col. 2 through line 4 of col. 3 a stent 10 comprising a plurality of hoops 11 formed from a continuous Nitinol wire comprising pairs of elongate elements forming apices abutting apices of adjacent hoops, which are connected by thermoplastic suture material 12. All hoops are axially aligned and of equal diameter.

3. Claims 20,22-24,31,54-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Fontaine US PN 5,370,683.

Fontaine discloses in figures 6, 9, 10, and 14 a stent comprised of a continuous wire formed into a plurality of interconnected (by welding lines 11-13 of col. 6) hoops at abutting apices or vertices (5,5' and 7,7') formed by pairs of elongate elements within each hoop. All hoops are axially aligned and of equal diameter.

4. Claims 20,22-25,39,43,44,47,54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff US PN 5,104,404.

Wolff discloses in figures 1 and 6 a stent comprised of a plurality of hoops 12 interconnected at apices formed by pairs of elongate elements within each hoop. Securing means 14 connects the apices of adjacent hoops. All hoops are axially aligned and of equal or different diameter (figure 6). Figure 1 shows the longitudinal ends of the stent being square to the long axis of the stent. As shown in Figure 1, each end portion of the stent, left 12 or right 12, may have a tubular coating of radiopaque material over element 14 (see lines 63-65 of col. 3).

5. Claims 20,22-24,31,39,54 are rejected under 35 U.S.C. 102(b) as being anticipated by Furui JP 4-25755.

Furui discloses in figure 1 a stent comprised of a plurality of hoops interconnected at apices formed by pairs of elongate elements within each hoop. Securing means connect the apices of adjacent hoops. All hoops are axially aligned, of equal or different diameter, and in a plane perpendicular to the longitudinal axis.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 45,46,48,49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff US PN 5,104,404 as applied to claims 54,43,44,47 above, and further in view of Piplani et al. US PN 5,824,039.

Wolff discloses the use of radiopaque markers in the form of tubes but does not expressly disclose the use of gold or platinum as the material or that the marker may be a wire. Piplani teaches a stented vascular graft having gold and platinum markers as well as markers in the form of wires (see lines 22-26 of col. 5 and lines 14-17 of col. 7) in order to provide visibility under fluoroscopy during implantation of the device.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the stent disclosed by Wolff to include gold or platinum as the material or to provide the marker in the form of a wire as taught by Piplani et al. in order to provide sufficient visibility under fluoroscopy during implantation of the device.



***Allowable Subject Matter***

8. Claims 27-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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